



04/18/00

PATENT

Case Docket No.: 99,198

ASSISTANT COMMISSIONER FOR PATENTS
 BOX PATENT APPLICATION FEE
 Washington, D. C. 20231
 Sir:

Date: April 18, 2000

Transmitted herewith for filing is the patent application of:

Inventor: Roger P. Jackson

For: ANTERIOR EXPANDABLE SPINAL FUSION CAGE SYSTEM

Enclosed are:



- ☒ Abstract of the Disclosure (1 page) and
☐ 53 Pages of Specification and Claims
☐ 9 Sheets of drawings
☒ Information Disclosure Statement
☒ Verified statements to establish small entity status under
 37 C.F.R. 1.9 and 37 C.F.R. 1.27
☒ The filing fee has been calculated as shown below:

FOR	NO. FILED	NO. EXTRA	RATE	SMALL ENTITY		RATE	OTHER THAN A SMALL ENTITY	
				FEE			FEE	
BASIC FEE	*****	*****	****	\$ 345	or	****	\$ 690	
TOTAL CLAIMS	30	- 20 = 10	x 9=	\$ 90	or	x18=	\$	
INDEP. CLAIMS	10	- 3 = 7	x39=	\$ 273	or	x78=	\$	
MULTIPLE DEPENDENT CLAIM PRESENTED			+130	\$	or	+260=	\$	
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☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 50-1253. A duplicate copy of this sheet is attached.

☒ Our check No. 1161 is also enclosed to cover, among other items, the above filing fee.

Respectfully submitted,

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VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
BY INVENTOR

Applicant: Roger P. Jackson

Serial No.:

Filed:

For: ANTERIOR EXPANDABLE SPINAL FUSION CAGE SYSTEM

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the above-entitled invention described in:

- (X) the specification filed herewith.
() application Serial No. _____, filed _____.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who, upon knowledge and belief, could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

Name of Concern: Not applicable
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I acknowledge my duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

4-13-2000

Date


Roger P. Jackson

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1 **ANTERIOR EXPANDABLE SPINAL FUSION CAGE SYSTEM**

2
3 **Background of the Invention**

4
5 The present invention is generally directed to an
6 apparatus and method for implanting an anterior installed
7 intervertebral fusion cage system which can be selectively
8 expanded anteriorly between two adjacent vertebrae to cause
9 them to change position relative to each other and produce a
10 normal alignment of the spine, while promoting fusion of the
11 vertebrae. More particularly, the invention discloses an
12 apparatus and method for surgically positioning an implant
13 having a fusion cage and one or more alternative expansion
14 caps which may be intercoupled with the cage to cause
15 expansion of the anterior portion of the cage to form an
16 adjustable wedge for alignment of two adjacent vertebral
17 bodies in accordance with a predetermined and desired spinal
18 curvature.

19 The implant of the present invention preferably
20 presents an anterior surface which is flush or slightly
21 recessed within the intervertebral joint, so that it does
22 not abrade or otherwise injure surrounding tissues. In

1 certain embodiments the device further includes structure
2 for supporting a substantial portion of the front of the
3 implant against a layer of harder, more compact bone at the
4 anterior surface of the vertebrae in order to reduce the
5 likelihood of subsidence of the device into the bone.
6 Adjacent cages between a pair of vertebrae are preferably
7 linked transversely to provide additional stabilization of
8 the vertebrae.

9 The spine is a column of stacked vertebrae, each having
10 a rounded, anterior element, or vertebral body which is
11 weight-bearing. The vertebral bodies are separated from
12 each other and cushioned by a series of fibrocartilage pads
13 or discs which impart flexibility to the spine. Aging,
14 injury and disease, such as degenerative disc disease, may
15 result in drying out or collapse of the discs, causing back
16 and leg pain. In some cases the disc or vertebra is damaged
17 beyond repair or must be removed for medical reasons.

18 While the spinal column appears to be straight when
19 viewed from an anterior or posterior vantage point, when
20 viewed laterally it is apparent that it is actually
21 comprised of four curved regions. In some congenital
22 conditions such as scoliosis and kyphosis, excessive

curvature or other displacement of the spinal vertebrae of the spine occurs.

Treatment of weakness, injury or improper curvature by removal of a disc and fusion of adjacent vertebral bodies (arthrodesis) has become relatively commonplace in recent years. More than 20,000 such interbody fusions of the lumbar region alone are now performed annually in the United States. Fusion of adjacent vertebral bodies is generally accomplished by implantation of a cage-like device in the intervertebral space. The cages are apertured, and include a hollow interior chamber which is packed with live bone chips, usually harvested from the patient's hip, less frequently from the leg, spine or ribs, or bone may be obtained from a bone bank. A bone substitute may also be employed. Following implantation, bone from each of the adjacent vertebrae grows through the apertures to fuse with the bone of the other vertebrae above and below the cage, thus stabilizing the area. The fusion process may take six to twelve months and it is desirable to stabilize both the vertebrae and the cages during the fusion process.

Once the fusion cage has been inserted, the angular orientation of the top and bottom surface of each cage is of importance, because this orientation determines the fixed

1 angular alignment of the facing surfaces of the two
2 vertebrae upon fusion. The cervical and lumbar curves each
3 present a region of normal anterior convexity and posterior
4 concavity or physiological lordosis. There is a need for an
5 implant which can be adjusted *in situ* to conform to and
6 maintain lordosis of the segments involved in the fusion or
7 adjusted to correct a preexisting deformity and to restore
8 or initiate proper angular vertebral alignment along the
9 spine.

10 Like most other bones, the bones of the spine and, in
11 particular, the vertebral bodies, consist of a core of
12 spongy, cancellous tissue surrounded by a rim of harder,
13 more compact bone. One problem associated with the
14 implantation of intervertebral fusion cages has been
15 eventual subsidence of the cage into the softer or spongier
16 bone that is normally on opposite sides of a disc following
17 implant. However, there is an anterior crescent of harder
18 bone close to the edge of the vertebral bodies. There is a
19 need for an implant which can be installed to provide
20 support along the full length of the upper and lower face of
21 the implant cage, for positioning the cage against a
22 substantial length of the harder, outer rim of bone to
23 provide better anterior support.

- 1 abrading or damaging the surrounding tissues subsequent to
- 2 insertion.

1 self-locking engagement. The expansion cap may also include
2 anterior upper and lower horizontal bone supporting
3 structure and an anterior recess. A pair of adjustable cage
4 units is fixedly intercoupled by a recessed link.
5 A set of caps is provided with each cap producing a
6 different expansion so that a surgeon may select the cap
7 best suited to provide the desired angular configuration
8 between adjacent vertebrae. The caps are also configured to
9 provide additional end plate support along a substantial
10 portion of the front edge of the vertebral bodies.

11 12 Objects and Advantages of the Invention 13

14 The principal objects of the present invention are: to
15 provide an improved method and apparatus for fusing together
16 adjacent vertebrae; to provide such a method and apparatus
17 for implanting an intervertebral fusion cage system for
18 introducing a bone graft between adjacent vertebrae; to
19 provide such a method and apparatus for implanting an
20 intervertebral fusion cage system while maintaining or
21 correcting the angular alignment of the vertebrae of the
22 spine; to provide a method and apparatus for implanting an
23 intervertebral dual cage system; to provide such a method

adjacent vertebral bodies together; providing such an apparatus and method which are relatively easy to use, inexpensive to produce and particularly well-suited for their intended usage.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of the invention.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

1 Brief Description of the Drawings

2

3 Figure 1 is a partially exploded perspective view of an

4 anterior expandable spinal fusion cage apparatus in

5 accordance with the present invention, illustrating a pair

6 of cages, a pair of expansion bolts and a linked expansion

7 cap unit.

8 Figure 2 is a fragmentary front elevational view of a

9 pair of adjacent vertebrae of a patient with the fusion cage

10 apparatus implanted between the vertebral bodies and showing

11 the expansion cap unit secured to the fusion cages.

12 Figure 3 is a cross-sectional view of one cage and

13 expansion cap of the apparatus, prior to final assembly with

14 one of the bolts positioned through the illustrated

15 expansion cap preparatory to engagement with a threaded bore

16 in a rear wall of the cage.

17 Figure 4 is a cross-sectional view similar to Figure 3,

18 illustrating the expansion cap in an expansion configuration

19 in the fusion cage, taken along line 4-4 of Fig. 1.

20 Figure 5 is an exploded perspective view at a reduced

21 scale showing an insertion tool aligned with a cage unit of

22 the invention.

Figure 7 is a side elevational view of a cage unit between a pair of adjacent vertebrae at a further reduced scale and showing the cage unit of Figure 6 in place in the intervertebral space and the insertion tool uncoupled and removed.

Figure 8 is an enlarged front elevational view of a first modified embodiment of a single implant in accordance with the invention.

Figure 9 is a cross-sectional view of the apparatus of Figure 8, illustrating one of a set of expansion caps secured to a fusion cage, taken along line 9-9 of Fig. 8.

Figure 10 is an enlarged, fragmentary side elevational view of the expansion cap of Figure 9.

Figure 11 is a cross-sectional view of the cage of Figure 9 coupled with a second of the set of extension caps configured to provide less anterior vertical height than the cap shown in Figure 9.

Figure 12 is a greatly enlarged, fragmentary side elevational view of the expansion cap of Figure 11.

Figure 13 is a cross-sectional view of the cage unit of Figure 8 coupled with a third of the set of expansion caps configured to provide less anterior vertical height than the cap shown in Figure 11.

Figure 14 is an enlarged, fragmentary side elevational view of the expansion cap of Figure 13.

Figure 15 is an exploded perspective view of a second modified embodiment of a fusion cage apparatus in accordance with the invention, illustrating a cylindrical fusion cage with a fixed stud, an expansion cap, a face plate and nuts.

Figure 16 is a cross-sectional view of the apparatus of Figure 15, preparatory to final installation of the expansion cap with respect to the cage, taken along line 16-16 of Fig. 15.

Figure 17 is a cross-sectional view similar to Figure 16, illustrating vertical expansion of a front of the cage produced by installation of the expansion cap.

Figure 18 is an exploded perspective view of a third modified embodiment of a fusion cage apparatus in accordance with the invention, illustrating a cage, an expansion cap and a bolt prior to installation.

Figure 19 is a front elevational view on a reduced scale of the cage of Figure 18.

Figure 20 is a cross-sectional view of the cage of Fig. 19, taken along line 20-20 of Fig. 19.

Figure 21 is a rear elevational view of the expansion cap of Figure 18.

Figure 22 is a cross-sectional view of the expansion cap, taken along line 22-22 of Fig. 18.

Figure 23 is a fragmentary diagrammatic view of a spinal column showing the cage of Figure 18 implanted with the expansion cap prior to final assembly on the cage.

Figure 24 is a view similar to Figure 23, illustrating the expansion cap assembled onto the cage to urge the top and bottom of the cage to form a wedge which engages the adjacent vertebrae and positions the vertebrae in proper physiological alignment.

Figure 25 is an enlarged exploded perspective view of a fourth modified embodiment of a fusion cage apparatus in accordance with the invention, illustrating an apparatus having a fusion cage and expansion cap configured for self-locking.

Figure 26 is a front elevational view on a reduced scale of the cage of Fig. 25.

Figure 27 is a cross-sectional view of the fusion cage of Fig. 25, taken along line 27-27 of Fig. 26.

Figure 28 is a rear elevational view of the expansion cap of Fig. 25.

Figure 29 is a cross-sectional view of the expansion cap of Fig. 25, taken along line 29-29 of Fig. 28.

Figure 30 is a fragmentary diagrammatic view of a spinal column showing the fusion cage of Figure 25 implanted with the expansion cap prior to expansion.

Figure 31 is a view similar to Figure 30, illustrating the expansion cap assembled on the cage and locking structures of the cage and expansion cap in mating engagement and with the cage expanded to form a wedge which supports the adjacent vertebrae in proper physiological alignment.

Figure 32 is a perspective view of a pair of the implanted cages as depicted in Figure 31, illustrating a cage link prior to assembly.

Figure 33 is a perspective view of the cages and cage link of Fig. 32 subsequent to final assembly.

Detailed Description of the Invention

As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

I. Dual Cage System With Fixed Link

Referring now to the drawings, an anterior expandible spinal fusion cage system in accordance with the invention is generally indicated by the reference numeral 1 and is shown in Figs. 1-6. An anterior view of a human spine showing the intervertebral region 2, which is the functional location of implantation of the fusion cage system 1, between upper and lower adjacent vertebral bodies or vertebrae 3 and 4, is shown in Fig. 2.

The expandible fusion cage system 1 broadly includes a pair of substantially identical, anteriorly inserted and

anteriorly expandable cages or implants 10 and 11 coupled with a cap unit or expansion module 12 by a pair of set screws or bolts 13 and 14. The description "anteriorly expandable" is used to indicate that anterior ends 15 (Fig. 4) of the cages 10 and 11 are expandable rather than posterior ends 16 thereof

Each of the implants 10 and 11 presents a generally truncated cylindrical overall configuration that is generally U-shaped when viewed from the side, having a horizontal central axis A extending the length thereof. An open-sided central chamber 20 is defined by a pair of spaced apart curvate top and bottom walls or legs 21 and 22, each having an outer surface 23 and 24. The walls 21 and 22 are apertured by a plurality of radial ports or windows 30, which open into the central chamber 20. The outer surfaces 23 and 24 include partial threads 31 which are interrupted by the windows 30.

The top and bottom walls 21 and 22 are coupled in spaced relationship by an enclosed rear wall, plate or web 32 having a central, threaded bore 33 and relieved corners. A front portion 34 of each of the cages 10 and 11 includes upper and lower margins 40 and 41 framing inwardly curved, upper and lower neck portions 42 and 43, each terminating at

3 The cages 10 and 11 are designed with curvate or
4 arcuate top and bottom walls 21 and 22 so that the cages 10
5 and 11 can be received in respective cylindrical grooves,
6 which are predrilled into the inferior and superior
7 surfaces, respectively of the pair of adjacent vertebral
8 bodies 3 and 4. Those skilled in the art will appreciate
9 that the cages may also be of a more generally rectangular
10 configuration for implantation by tapping into the
11 intervertebral region 2, or they may be constructed in any
12 other geometric configuration which is suitable for
13 implantation in an intervertebral region 2.

14 The expansion module 12 includes a pair of identical
15 rectangular expansion caps or wedges 50 and 51 intercoupled
16 in parallel alignment by a generally rectangular link 52.
17 The link 52 is preferably recessed a distance of from about
18 one to about five millimeters from faces 53 of the expansion
19 caps in order to maintain an overall flush anterior profile
20 of the implanted cage system 1. Those skilled in the art
21 will appreciate that in certain forms the link 52 may also
22 connect the caps 50 and 51 at a slightly convergent or
23 divergent angle (that is the axis of the cages 10 and 11 may

toe in or converge or toe out and diverge from the anterior side or may even be skewed relative to each other), such that when the cages 10 and 11 are installed at corresponding angles, the cages 10 and 11 will be more difficult to disturb and also preferably provide a slight loading or bias to the cages 10 and 11 during tightening of the caps 50 and 51 to further stabilize the intervertebral cage system 1.

The link 52 is sized to maintain the implants at a selected spacing, to enhance lateral stability and to permit a bone graft to grow from the chamber 20 outwardly, through the windows 30 and into the central portion of the intervertebral region 2, to fuse the vertebral bodies 3 and 4 together.

The expansion caps 50 and 51 each present a generally rectangular, planar face 53 having a central aperture 54, which includes a conical countersink 55 to permit flush installation of the bolts 13 and 14 having correspondingly shaped heads 62 into the caps 50 and 51. The expansion caps 50 and 51 are of unitary construction, each including a wedge 60 having a generally frustotriangular cross section coupled with a base 61 having a generally rectangular cross section. The expansion cap bases 61 are sized for insertion between the upper and lower margins 40 and 41 at the front

1 of each of the cages 10 and 11. A beveled geometric
2 configuration of the wedge 60 permits sliding engagement of
3 the wedge 60 with surfaces of the necks 42 and 43 of the
4 cages 10 and 11, which force the walls or legs 21 and 22
5 apart as the base 61 is snugged against the implant
6 shoulders 44 and 45, which serve as stops.

7 The bolts 13 and 14 are sized and shaped to be received
8 in the expansion cap apertures 54, with a screw head 62
9 received against the expansion cap countersink 55. Each
10 screw also includes a shank 63 of reduced diameter and
11 terminating in a threaded surface 64, which is operably
12 received in a respective cage matingly threaded bore 33.
13 Each screw head 62 also includes an opening 70 configured to
14 receive a driving tool such as a wrench, screwdriver or the
15 like (not shown).

16 The cages 10 and 11, expansion module 12, and bolts 13
17 and 14 are constructed of a strong, inert material having
18 some elasticity such as a stainless steel or titanium alloy,
19 although carbon fiber, porous tantalum or any other
20 biocompatible material or combination of materials may be
21 employed.

22 An insertion tool 71 for use in association with
23 certain embodiments of the invention is depicted in Figs.

5-7 ind includes a handle 72 coupled with a centrally bored shank portion 73 and a bolt 74 sized for registry within the bore of the shank 73. The handle 72 is centrally apertured for insertion of the bolt 74 therethrough and through the bored shank 73. The bolt 74 includes a hex type head 75 at one end and a threaded surface 76 at the opposed end. The portion of the shank 73 remote from the handle 72 is expanded to correspond to the diameter of the implant cage 10. A pair of opposed grooves 80 are machined into the expanded shank 73, leaving corresponding opposed lands 81 so that the shank 73 is sized and shaped to slidably but snugly mate with the fusion cage 10. The lands 81 include threads 82, which correspond to the threads 31 of the top and bottom walls 21 and 22 of the cage 10.

In use, the anterior surface of a selected intervertebral region 2 of the spine of a patient is surgically exposed. The soft tissues are separated, the disc space is distracted and the disc is removed, along with any bone spurs which may be present. The spaced upper and lower vertebral bodies 3 and 4 to be stabilized and fused are then anteriorly drilled between to form a pair of opposed cage receiving grooves 84 having fixed spacing and alignment predetermined to match the alignment of the cages

8 An implant insertion tool 71 is positioned adjacent a
9 fusion cage 10 so that the cage top and bottom walls 21 and
10 22 are aligned with the grooves 80 in the tool. The tool 71
11 and the cage 10 are urged toward each other until the cage
12 walls 21 and 22 are received in the grooves 80 and the tool
13 threads 83 are in registry with the implant cage threads 31,
14 to form a continuously threaded surface as shown in Fig. 6.

15 The bolt 74 is then inserted through the apertured
16 handle 72 and advanced rearward until it contacts the
17 threaded bore 33 in the rear wall of the implant 32. A
18 driving tool such as a socket wrench (not shown) is employed
19 to rotate the bolt 74 until the threaded surface 76 of the
20 bolt is matingly received in the bore 33.

21 A user then grasps the handle 72 and positions the tool
22 71 and intercoupled cage 10 adjacent the intervertebral bore

3 When the cage 10 is properly positioned, a driving tool
4 (not shown) is employed to rotate the bolt head 75 counter
5 clockwise, while the cage 10 is immobilized, until the
6 threaded surface of the bolt 76 is disengaged from the
7 threads of the implant bore 33. The insertion tool 71 is
8 then removed from the intervertebral bore 84 and the cage 10
9 remains in place. This procedure is repeated for
10 installation of a second cage 11 at a predetermined location
11 spaced from the first cage 10. Although the curvate outer
12 surfaces 21 and 22 of the cages 10 and 11 are particularly
13 well suited for such threaded insertion into a predrilled
14 intervertebral set of grooves 84, it is foreseen that they
15 may also be inserted either by tapping into a predrilled set
16 of grooves 84 or by tapping directly into the distracted
17 intervertebral region 2.

As best shown in Figs. 3 and 4, the expansion module 12 is installed anteriorly, onto the cages 10 and 11 by alignment of the base 61 of each expansion cap 50 and 51 between a respective upper and lower cage margins 40 and 41. A respective set screw or bolt 13 or 14 is inserted through

1 the aperture 54 of each expansion cap 50 and into the
2 threaded bore 33 in the rear wall 32 of the cages 10 and 11.

3 The bolts 13 and 14 are then tightened to bring the
4 rear surfaces of the base 61 of each expansion cap 51 into
5 sliding engagement with the upper and lower implant neck
6 portions 42 and 43. Continued tightening of the bolts 13
7 and 14 causes each base 61 to wedge the front portions of
8 the top and bottom cage walls 20 and 21 apart, so that the
9 cages 10 and 11 each begin to assume a generally
10 trapezoidal shape when viewed from the side. The bolts 13
11 and 14 are further tightened until the rear surface of each
12 expansion cap base 61 contacts each respective upper and
13 lower shoulder 44 and 45, which cooperatively serve as a
14 stop. In this manner, the shoulders 44 and 45 serve to
15 prevent greater distraction of the disc space or region than
16 is desired.

17 The expansion caps 50 and 51 are sized so that, upon
18 coupling with the cages 10 and 11, they form a wedge which
19 supports the vertebral bodies 3 and 4 at the proper height
20 as well as a desired angular alignment to achieve
21 physiological lordosis at the intervertebral region 2. While
22 expansion caps 50 and 51 of a selected size are depicted in
23 Figs. 1-4, those skilled in the art will appreciate that

1 caps producing varying degrees of expansion may be employed
2 to produce the desired effect.

3 The surgeon then transplants a quantity of packed bone
4 cells or a suitable bone substitute material or bone growth
5 enhancer into each of the chambers 20, as well as into the
6 area 2 between the implant cages 10 and 11. The bone cells
7 may be introduced into the chambers 20 by a lateral approach
8 through the open area between the top and bottom implant
9 walls 21 and 22. Alternatively, the bone cells may be
10 introduced into the chambers 20 by an anterior approach
11 through the implant front 34 prior to installation of the
12 expansion module 12 or by a combination of these methods.
13 Bone for use in the graft may be preferably harvested from
14 the patient as live bone, from a bone bank or from a
15 cadaver. Demineralized bone matrix, bone morphogenic
16 protein or any other suitable material may also be employed.

17 Following implantation, the bone grows between
18 vertebrae 3 and 4 through the windows 30 with the bone in
19 the chambers 30 and between and around the cages 10 and 11
20 to fuse the vertebral bodies 3 and 4 together.

21 II. Alternate Fusion Cage System

22 The structure of a first modified embodiment of an
23 anterior expandable spinal fusion cage system in accordance

27

8 The cage 102 presents a generally truncated cylindrical
9 overall configuration that is generally U-shaped when viewed
10 from the side, including an open-sided central chamber 111,
11 bounded by a pair of curvate top and bottom walls 112 and
12 113. The chamber 111 is further enclosed by a rear wall
13 114.

14 The front portion 121 of the cage 101 includes upper
15 and lower margins 122 and 123 framing inwardly curved upper
16 and lower neck portions 124 and 125, each portion
17 terminating at a shoulder 131 and 132. The cage front
18 portion 121 opens into the central chamber 111.

The large, intermediate and small expansion caps 103, 104 and 105 are of unitary construction, each including a wedge-shaped head 133 having a generally frustotriangular configuration when viewed from the side, coupled with a base 134 having a generally trapezoidal configuration. An angle

1 A is formed by the junction of the head 133 and base 134.
2 The size of the angle A generally conforms to the angle at
3 the cage front 121, but the alignment varies depending upon
4 degree of expansion of the cage 102.

5 The rear surface of the expansion cap head 133, which
6 extends from base 134, slidably engages the surfaces of the
7 implant neck 124 and 125, forcing them apart until the base
8 134 rests against the shoulder stops 131 and 132.

9 In use, the fusion cage system 101 is implanted in a
10 manner substantially similar to the embodiment previously
11 described. Initially, the smallest expansion cap 105 is
12 selected for coupling with an implant 102. The bolt 106 is
13 then tightened until the rear surface of the expansion cap
14 base 134 contacts the upper and lower shoulders 131 and 132
15 and the rear surfaces of the expansion cap head 133 rests
16 against the upper and lower neck surfaces 124 and 125.

17 In the set of caps depicted, the first cap 105 produces
18 no expansion in the anterior portion of the cage 102, but
19 rather simply stabilizes the cage 102 where no expansion is
20 needed. That is, the cage 102 upper wall 112 and lower wall
21 113 remain parallel after insertion. The surgeon then
22 checks the alignment of the vertebrae and, if greater
23 expansion is required, the first cap 105 is removed and the

1 next larger cap 104 is inserted. The cap 104 causes the
2 cage upper wall 112 and lower wall 113 to be nonparallel and
3 wider to the front, see Fig. 11. If the surgeon is then
4 satisfied with the alignment of the vertebrae, the cap 104
5 is left in place. If greater frontward expansion is
6 required, the cap 104 is removed and the cap 103 is
7 inserted. The cap 103 produces greater anterior expansion
8 of the cage 102, see Fig. 9, providing a wedge-shaped
9 configuration of the cage 102 and thus angularly realigning
10 the vertebrae above the cage 102 relative to those below the
11 cage 102 to cause normal physiological lordosis.

12 In particular, as is best shown in Figs. 9 and 10, upon
13 installation, the expansion caps 103 and 104 each cause the
14 fusion cage 102 to form a generally trapezoidal
15 configuration when viewed from the side. When used to
16 expand, the larger the expansion cap, the greater the
17 distance the anterior portions of the top and bottom walls
18 112 and 113 are wedged apart and the greater the angle
19 associated with the intersection of planes passing through
20 the faces of the adjacent vertebral bodies and the larger
21 the central chamber 111 for receiving the bone graft. Thus,
22 either by trial or by experience, the surgeon can adjust the
23 angle of planes passing through the facing surfaces of

1 adjacent vertebrae *in situ* to achieve a desired angular
2 alignment of vertebrae for producing a desired curvature of
3 the spine.

4 **III. Cylindrical Fusion cage System With Fixed Screw**

5 A second modified embodiment of an anterior expandable
6 spinal fusion cage system in accordance with the invention
7 is generally represented by the reference numeral 201 and is
8 shown in Figs. 15-17 to include an expandable implant or
9 fusion cage 202, an expansion cap assembly 203 and a cover
10 assembly 204. The cage 202 has a generally open-sided
11 cylindrical configuration, having a central axis C, and
12 upper and lower walls 210 and 211, discontinuously
13 circumscribing a central chamber 212. Each of the walls 210
14 and 211 is apertured by a plurality of radially aligned
15 windows 220. The walls 210 and 211 also each include
16 partial threads 221, which are interspaced by the windows
17 220.

18 The cage 202 has an enclosed rear wall 222, which is
19 perpendicularly coupled at the center with a post or stud
20 223. The implant 202 has upper and lower front ends 230 and
21 231 coupled with upper and lower axially convergent beveled
22 surfaces 232 and 233. The front ends 230 and 231 open into
23 the central chamber 212.

1 The post 223 is coaxial with axis C throughout the
2 length of central chamber 212, and includes a shank 240,
3 which terminates in a threaded surface 241.

4 The expansion cap 203 is generally frustoconical in
5 shape and includes an axially converging circumscribing wall
6 242 intercoupling a rear wall 243, and an outer, radially
7 expanded face 244. The rear wall 243 has an aperture 245 to
8 receive the post 223. The face 244 is sized and configured
9 for registry with the implant upper and lower front ends 230
10 and 231 upon installation.

11 The cover assembly 204 includes a generally lozenge-
12 shaped cover plate 250 and a pair of retaining nuts 251 and
13 252. The cover plate 250 includes upper and lower parallel
14 linear or planar surfaces 253 and 254 and a central,
15 generally circular recess 255 for receiving the nut 252.
16 The recess 255 serves to receive the nut 252 and prevent the
17 nut 252 from projecting into the adjacent tissues, where it
18 might cause irritation or damage. The center of the recess
19 255 includes an aperture 256, for receiving the post 223.
20 It is foreseen that the cap 203 and cover assembly 204 may
21 be manufactured as a single unit.

22 In use, the fusion cage 202 of the cage system 201 is
23 inserted into a predrilled threaded set of grooves forming a

1 bore-like structure in and between adjacent vertebral bodies
2 and a bone graft is introduced in much the same manner as
3 the embodiments previously described. As best shown in Fig.
4 16, once the cage 202 is implanted, the expansion cap 203 is
5 installed over the post 223, so that the rear surface of the
6 wall 242 rests against the front end surfaces 230 and 231.

7 A first nut 251 is threaded onto the threaded surface
8 of the post 241 and is snugged against the rear wall of the
9 expansion cap 243, forcing the upper and lower walls 210 and
10 211 apart, so that the implant cage 202 assumes the
11 generally wedge shape depicted in Fig. 17. The nut 251 is
12 tightened until the rearward approach of the face ring rear
13 wall 243 is stopped by contacting the front end surfaces 230
14 and 231.

15 The cover plate 250 is installed over the expansion cap
16 by positioning the central aperture 256 over the post 223
17 and threading the second nut 252 onto the threaded surface
18 of the post 241. The nut 252 is tightened until the rear
19 surface of the cover plate 250 is snug against the surface
20 of the face ring 244.

21 Advantageously, the fusion cage system 201 is installed
22 to a slightly inset depth between a pair of adjacent
23 vertebrae such as partially illustrated vertebra 246, so

1 that the cover plate upper and lower horizontal surfaces 253
2 and 254 provide continuous horizontal support for the
3 harder, anterior bone margins of the adjacent vertebral
4 bodies. In this manner, the system 201 minimizes subsidence
5 of the cage 202 into the bone 246.

6 IV. Rectangular Fusion Cage System With Anterior Support

7 A third modified embodiment 301 of an anterior
8 expandable spinal fusion cage system in accordance with the
9 invention is shown in Figs. 18-24 and includes a cage
10 implant or fusion cage 302, coupled with an expansion cap
11 303 by a bolt 304. The cage 302 is generally U-shaped when
12 viewed from the side and presents a generally rectangular
13 configuration overall, having upper, lower and rear walls
14 310, 311 and 312 collectively defining an open-sided central
15 chamber 313. The walls 310 and 311 each have an outer
16 surface 314 and 315, respectively, and include an elongate
17 central slot 320, which extends lengthwise and opens into
18 the central chamber 313. The outer surfaces 314 and 315
19 each include a series of ridges 321, which are interrupted
20 by the slot 320.

21 The rear wall 312 includes a central, threaded bore
22 322. The cage 302 has upper and lower front ends 330 and

1 331 and upper and lower beveled or slanted surfaces 332 and
2 333.

3 The expansion cap 303 is generally rectangular when
4 viewed from the front, and includes a front face 340
5 perpendicularly joined with generally horizontal top and
6 bottom walls 341 and 342 and planar side walls 343. The
7 sidewalls 343 converge inwardly and join with a generally
8 square shaped rear wall 344, having a central bore 350. The
9 bore 350 includes a conical countersink 351 to permit
10 installation of the bolt 304, flush with the rear wall 344.

11 The bolt 304 is sized to be operably received first by
12 the expansion cap bore 350 and then through the matingly
13 threaded rear wall bore 322. The bolt 304 includes a head
14 352 and a shank 353, which terminates in a threaded surface
15 354. The bolt head 352 includes an opening 355 configured
16 to receive a driving tool such as an Allen wrench (not
17 shown).

18 In use, the fusion cage system 301 is installed into an
19 intervertebral region 360 of the spine 361 of a patient as
20 shown in Figs. 23 and 24. Anterior exposure of the
21 intervertebral joint 361, distraction of an affected disc
22 362 and preparation of the space between a pair of adjacent
23 vertebral bodies 363 is performed as previously described.

1 Because the rectangular configuration of the implant
2 cage 302 is best suited to installation by tapping into the
3 interbody space it is not necessary to drill between the
4 adjacent vertebral bodies 363. The implant cage 302 is
5 inserted so that the front 323 is situated at a
6 predetermined location which is slightly posterior to the
7 outer bone margins 364 of the adjacent vertebral bodies 363.

8 The expansion cap 303 is installed anteriorly, onto the
9 cage 302 by alignment of the sidewalls 343 between the upper
10 and lower ends 330 and 331. The bolt 304 is aligned with
11 and operably received in the expansion cap bore 350 as well
12 as the fusion cage bore 322. A driving tool (not shown) is
13 inserted into the opening 355 and employed to rotate the
14 bolt 304 to cause the expansion cap sidewalls 343 to
15 slidably engage the upper and lower beveled surfaces 332
16 and 333 of the fusion cage 302. Continued tightening of the
17 bolt 304 biases the implant upper and lower walls 310 and
18 311 apart into a wedge shape. The bolt 304 is tightened
19 until the cap face 340 is snugged against the upper and
20 lower ends 330 and 331 of the fusion cage 302. In this
21 configuration, the horizontal top and bottom expansion cap
22 walls 341 and 342 engage and abut against the outer bone
23 margins of the vertebral bodies 364. In this manner, the

1 top and bottom walls 341 and 342 of the expansion cap
2 provide continuous horizontal support for the harder,
3 anterior margin of bone 364 of the adjacent vertebral bodies
4 363.

5 It is foreseen that the cage of the present embodiment
6 may be utilized with cages of the type shown in the previous
7 embodiment, including a set of caps producing different
8 expansions, caps with linear or near linear vertebra end
9 plate support and pairs of caps that are connected together
10 by a cross link.

11 V. Rectangular Fusion Cage System With Cross Link

12 Figs. 25-33 illustrate a fourth modified embodiment 401
13 of an anterior expandable spinal fusion cage system in
14 accordance with the invention. The structure and function
15 of the fourth embodiment 401 is in many ways similar to that
16 of the embodiment 301 previously described, with the major
17 distinction being that the system incorporates a cross
18 linking feature.

19 Figs. 30 and 31 depict installation of the system 401
20 in a spinal column 402 having an intervertebral region 403.

21 The system 401 includes a pair of implant cages 411 and
22 412 and a pair of expansion caps 413 and 414 joined by a
23 cross link 415. The implants 411 and 412 are similar to the

1 implant cage 302 of the previous embodiment in that each
2 presents a generally rectangular cross section which is best
3 suited for installation by tapping into the intervertebral
4 region 403.

5 The implant cages 411 and 412 are generally U-shaped
6 when viewed from the side, and each includes a top wall 421,
7 bottom wall 422, and rear wall 423, defining an open-sided
8 central chamber 424 there between. The rear wall 423
9 includes a central bore 425 and the walls include a
10 plurality of windows 426, which open into the central
11 chamber 424.

12 The implants 411 and 412 include upper and lower front
13 ends 431 and 432, which differ from those of the embodiment
14 previously described in that each is stepped toward a
15 channel or groove 433 and 434 formed in the top and bottom
16 walls 421 and 422, respectively. The upper and lower front
17 ends 431 and 432 are coupled with beveled surfaces 435 and
18 436.

19 The expansion caps 413 and 414 are of identical
20 construction and are similar to the expansion caps of the
21 previous embodiment in that they are generally rectangular
22 when viewed from the front, include a front face 441,
23 horizontal top and bottom walls 442 and 443, convergent

sidewalls 444 and a rear wall 445. The expansion caps 413 and 414 differ from those previously described in that the horizontal top and bottom walls 442 and 443 each extend rearwardly to include top and bottom flanges 451 and 452 along the length thereof.

6 The caps 413 and 414 include in each rear wall 445 a
7 threaded bore 453 for receiving a bolt 454, but do not
8 include a countersink for recessing the bolt. The cross
9 link 415 is generally U-shaped and includes a pair of
10 apertures 455 and 456 for receiving the bolt 454 in feet 458
11 thereof.

The modified apparatus 401 is installed by tapping a pair of implant cages 411 and 412 into an intervertebral region 403 in a predetermined, spaced relationship. A pair of expansion caps 413 and 414 is aligned over the cages 411 and 412 in a manner similar to that of the apparatus 401 of the previous embodiment. A connector link 415 is installed in overlapping relationship between the expansion caps 413 and 414, so that each of the apertures 455 and 456 are in alignment with one of the bores 453. The apertures and aligned bores 453 receive a pair of bolts 454. Tightening advances the bolts 454 rearwardly and into the aligned bores 435 in the rear walls 423 of the cages 411 and 412. The

1 bolts 454 are tightened until the top flanges 451 and 452 of
2 the expansion caps 413 and 414 are received into the upper
3 and lower implant cage channels 443 and 444, in mating
4 engagement. In this manner, a pair of implant cages 411 and
5 412 are joined in spaced relationship at a predetermined
6 angle and locked into place.

7 It is to be understood that while certain forms of the
8 present invention have been illustrated and described
9 herein, it is not to be limited to the specific forms or
10 arrangement of parts described and shown.

11

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. An implant apparatus for positioning between adjacent vertebrae and comprising:
 - a) a fusion cage having a pair of legs interconnected at one end each by a wall, said legs having free ends opposite said wall, said cage being adapted for implanting between said adjacent vertebrae with outer surfaces of said legs engaging said vertebrae respectively;
 - b) an expansion cap having a wedge member positioned between said free ends of said legs in such a manner that movement of said wedge member toward said wall urges said leg free ends apart; and
 - c) a fastener engaged between said wedge member and said wall and operable to selectively urge said wedge member toward said wall.

2. The apparatus according to Claim 1 wherein:
 - a) said expansion wedge member is selected from a set of a plurality of interchangeable wedge members;
and
 - b) each wedge member being sized to form said apparatus into a different predetermined angle.
3. The apparatus according to Claim 1 wherein:
 - a) said cage member includes an interior chamber for receiving bone fragments; and
 - b) a plurality of radially positioned apertures for permitting bone fragments in said chamber to join and fuse with bone in the adjacent vertebrae.
4. An apparatus for positionally stabilizing adjacent vertebrae of a spine by promotion of bone fusion between the adjacent vertebrae, said apparatus comprising:
 - a) an implant for implanting between a pair of adjacent vertebrae, said implant adapted to promote bone growth between the adjacent vertebrae;

- b) an expansion cap coupled with said implant for expanding an anterior portion of said implant for forming said implant into a predetermined angle to cause alignment of the adjacent vertebrae; and
 - c) a fastener mechanism operably securing said expansion cap to said implant during use.
5. The apparatus according to Claim 4 wherein:
- a) said expansion cap is selected from a set including a plurality of expansion caps; and
 - b) each cap of said set being sized to form said implant into a different predetermined angle.
6. The apparatus according to Claim 4 wherein:
- a) said implant includes an interior chamber for receiving bone fragments; and
 - b) a plurality of radially positioned apertures for permitting bone fragments in said chamber to join and fuse with bone in the adjacent vertebrae.
7. An apparatus for positionally stabilizing adjacent vertebrae of a spine by promotion of bone fusion

9. The apparatus according to Claim 7 wherein:

a) said expansion unit includes a pair of expansion caps coupled by a connector.

10. The apparatus according to Claim 9 wherein:

- a) each of said expansion caps includes a face; and
- b) said connector is recessed posteriorly from said expansion cap faces.

11. An apparatus for positionally stabilizing adjacent vertebrae of a spine by promotion of bone fusion between the adjacent vertebrae, said apparatus comprising:

- a) an anteriorly expandable implant adapted to promote bone growth between the adjacent vertebrae;
- b) an expansion member coupled with said implant for expanding an anterior portion of said implant for forming said implant into a predetermined angle to cause alignment of the adjacent vertebrae;
- c) a cover assembly having upper and lower support surfaces for supporting an anterior region of the adjacent vertebrae; and

- d) a fastener mechanism operably securing said cover assembly and said expansion member to said implant during use.

12. The apparatus according to Claim 11 wherein:

- a) said implant includes a rear wall; and
- b) said fasteners include a bolt member fixedly coupled with said rear wall and extending forwardly therefrom for coupling with a nut for securing said cover and said expansion member to said implant.

13. The apparatus according to Claim 11 wherein:

- a) said implant includes an interior chamber for receiving bone fragments; and
- b) a plurality of radially positioned apertures for permitting bone fragments in said chamber to join and fuse with bone in the adjacent vertebrae.

14. An apparatus for positionally stabilizing adjacent vertebrae of a spine by promotion of bone fusion between the adjacent vertebrae, said apparatus comprising:

- a) an implant for implanting between a pair of adjacent vertebrae, said implant adapted to promote bone growth between the adjacent vertebrae;
- b) an expansion cap coupled with said implant for expanding an anterior portion of said implant to a predetermined angle to cause alignment of the adjacent vertebrae; and
- c) said expansion cap including upper and lower support surfaces for supporting an anterior region of said adjacent vertebrae.

15. The apparatus according to Claim 14 wherein:

- a) said expansion cap includes a recess for receiving a fastener to secure said cap to said implant.

16. The apparatus according to Claim 14 wherein:

- a) said implant includes an interior chamber for receiving bone fragments; and

- b) a plurality of radially positioned apertures for permitting bone fragments in said chamber to join and fuse with bone in the adjacent vertebrae.

17. The apparatus according to Claim 14 wherein:

- a) said expansion cap and said implant include structure for cooperatively locking together said cap and said implant when fully joined.

18. An apparatus for stabilizing between adjacent vertebrae of a spine by promotion of bone fusion between the adjacent vertebrae, said apparatus comprising:

- a) a pair of anteriorly expandable implants for implanting in side-by-side relationship between a pair of adjacent vertebrae, each of said implants adapted to promote bone growth between the adjacent vertebrae;
- b) a pair of expansion caps, each expanding an anterior portion of one of said implants for forming said implants into a predetermined angle to cause alignment of the adjacent vertebrae;

19. The apparatus according to Claim 18 wherein:

a) said expansion caps and said implants each include structure for cooperatively locking together said caps and said implants such that said implants are aligned in nonparallel configuration with respect to each other.

20. The apparatus according to Claim 18 wherein:

- a) each of said implants includes an interior chamber for receiving bone fragments; and
- b) a plurality of radially positioned apertures for permitting bone fragments in said chamber to join and fuse with bone in the adjacent vertebrae.

21. A method of stabilizing and promoting bone fusion between two adjacent vertebrae comprising the steps of:
 - a) providing an implant adapted to promote bone growth;
 - b) implanting said implant between a pair of adjacent vertebrae;
 - c) providing an expansion cap adapted for expanding an anterior portion of said implant to a predetermined angle; and
 - d) coupling said expansion cap with said implant and expanding said implant to a predetermined angle to cause alignment of the adjacent vertebrae.
22. The method according to Claim 21 wherein said step of providing an expansion cap includes the step of:
 - a) providing a plurality of expansion caps of graduated sizes.
23. The method according to Claim 22 including the steps of:
 - a) selecting a first expansion cap;
 - b) coupling said first expansion cap with said implant and expanding said implant; and

c) removing said first expansion cap and repeating steps (a) through (c) with subsequent longer expansion caps, until said implant is expanded to a predetermined angle to cause alignment of the adjacent vertebrae.

24. In an expandable fusion cage apparatus having a fusion cage for insertion between vertebrae, the improvement comprising:

a) a set of interchangeable expansion caps of different sizes and cooperating with said fusion cage to allow a surgeon to selectively adjust the expansion of said fusion cage.

25. In a fusion cage apparatus having a fusion cage for insertion between vertebrae, the improvement comprising:

a) an expansion cap for expanding said cage to a selected degree of expansion.

26. The apparatus according to Claim 25 wherein:

for implanting between said adjacent vertebrae with outer surfaces of said legs engaging said vertebrae respectively; and

- b) an expansion cap positioned between said free ends of said legs in such a manner that movement of said cap toward said wall urges said leg free ends apart and increase the spacing between the top and bottom of at least one end of said implant, said cap not expanding the size of said implant from side to side.

[illegible][illegible]

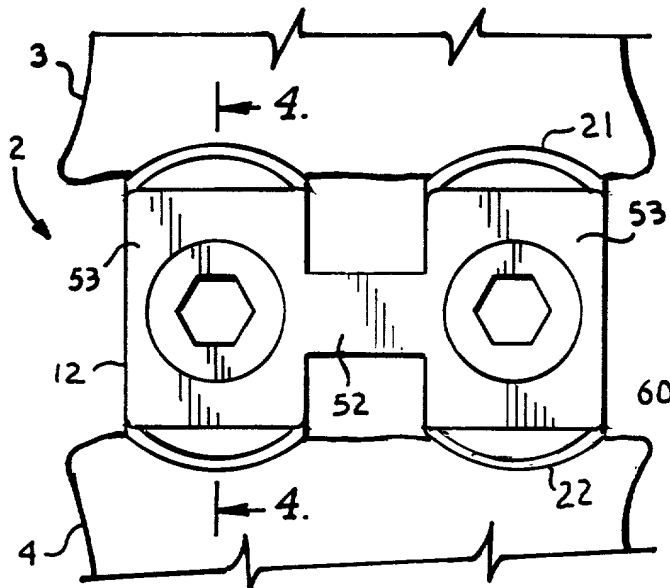


Fig. 2.

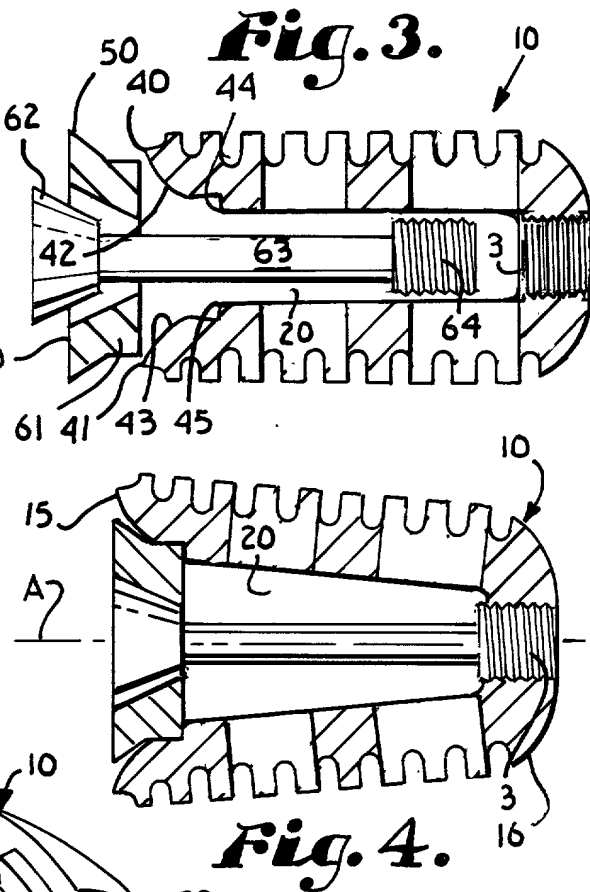
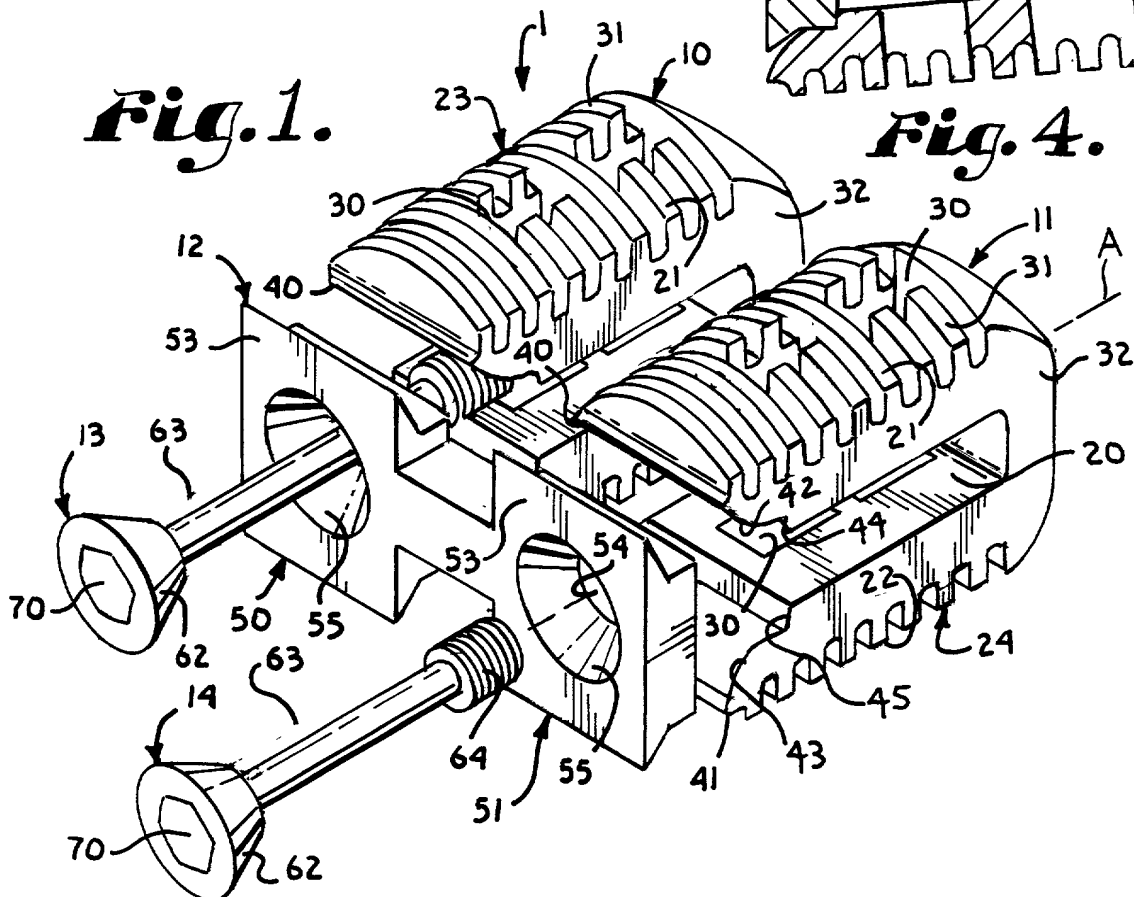
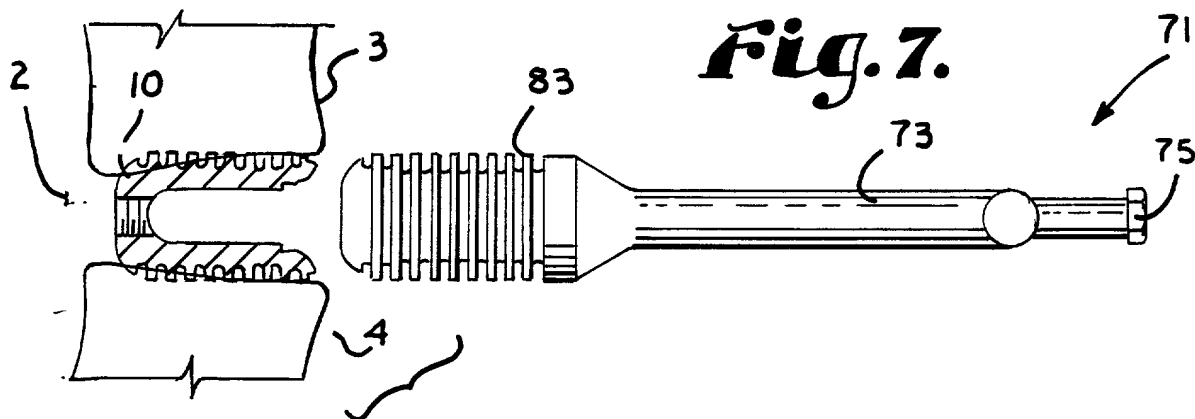


Fig. 4.





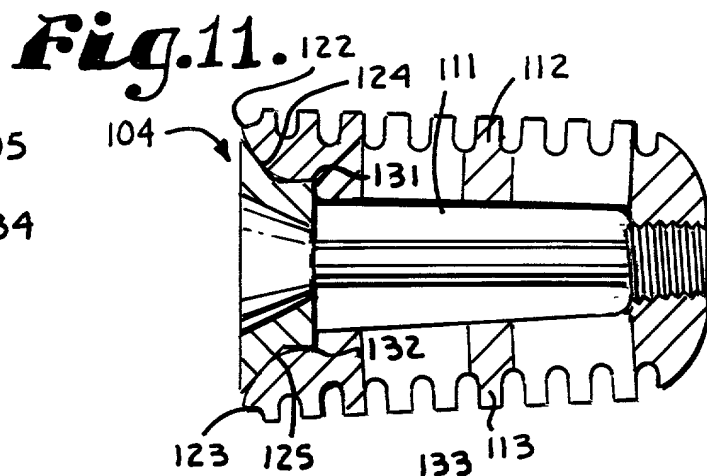
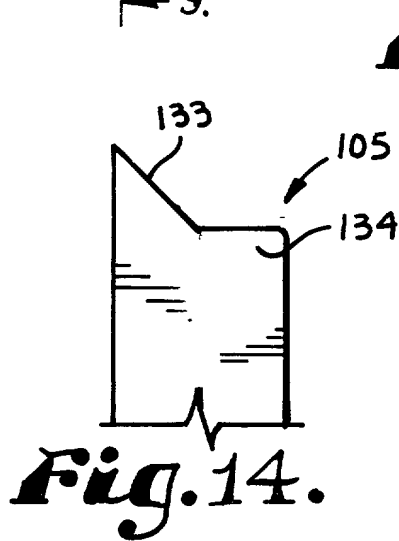
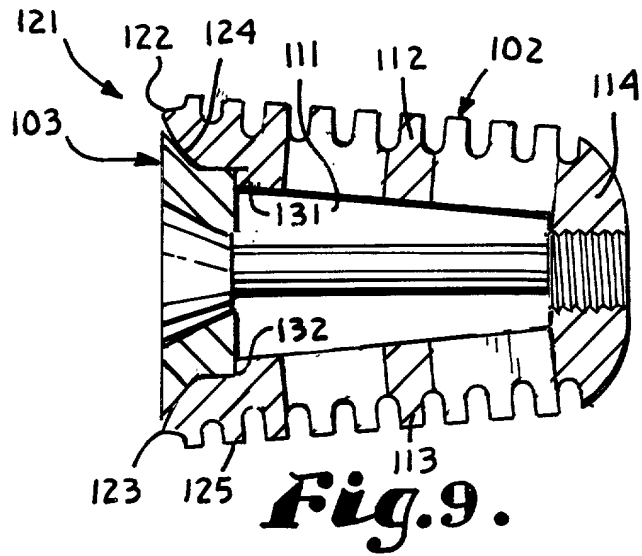
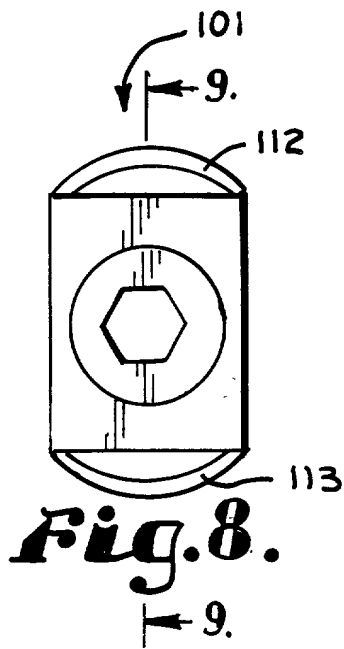


Fig. 13.

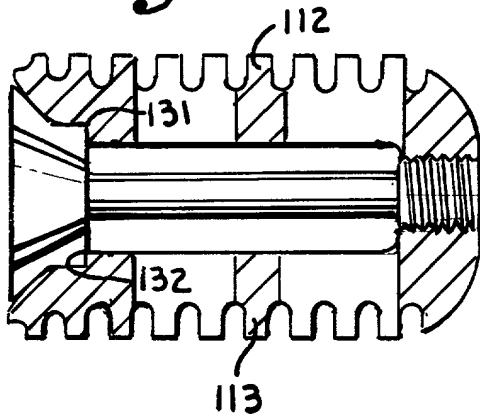
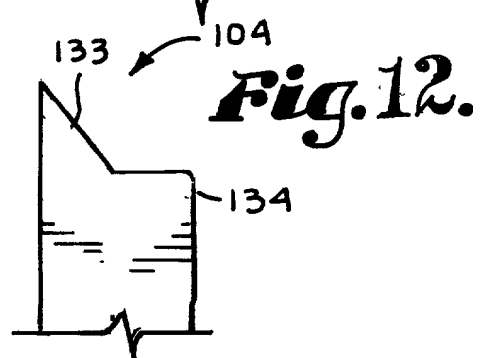
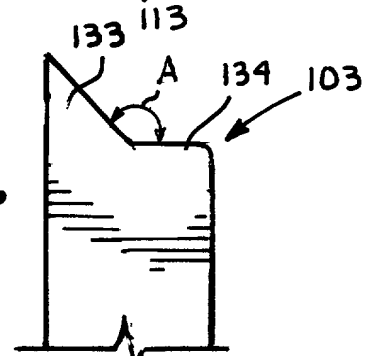


Fig. 10.



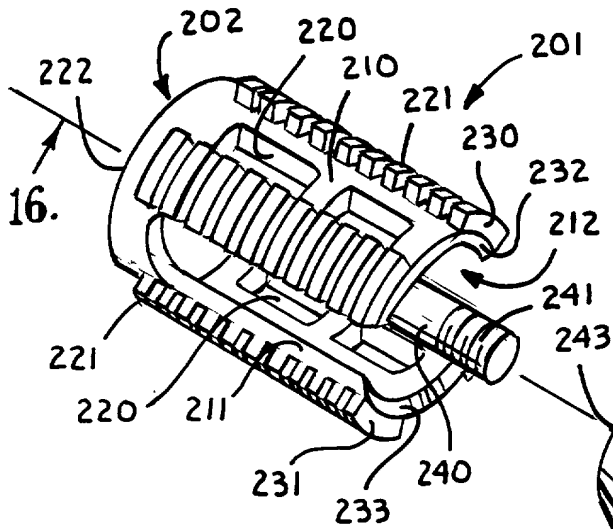


Fig. 15.

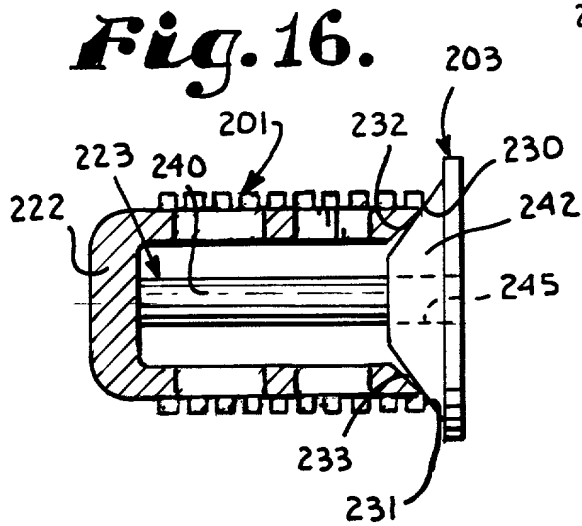
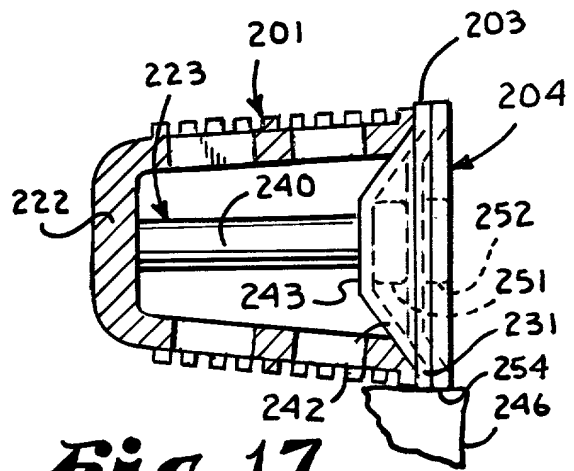


Fig. 16.



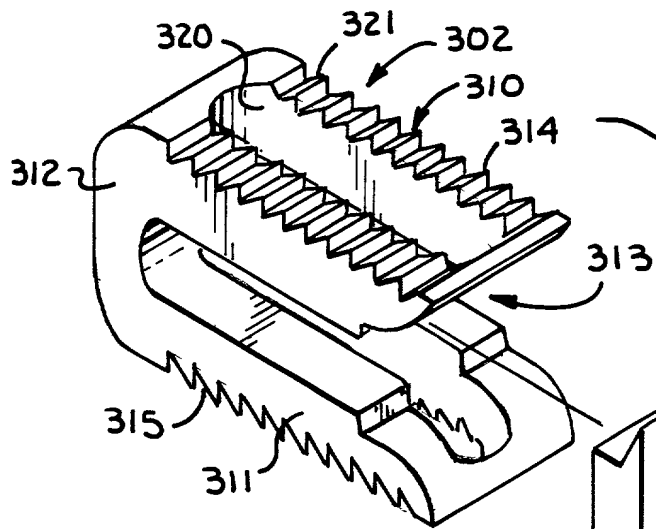


Fig. 18.

Fig. 19.

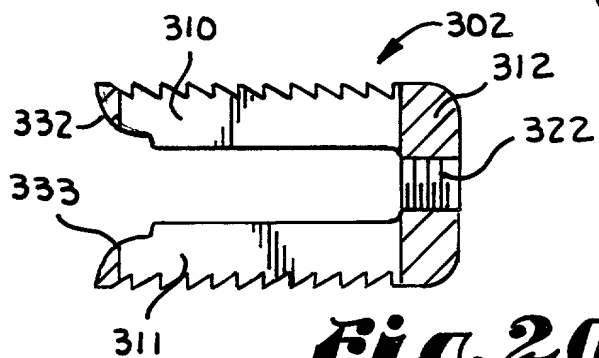
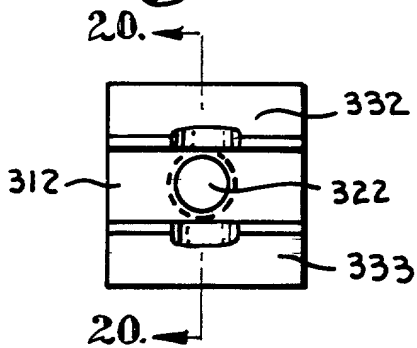


Fig. 20.

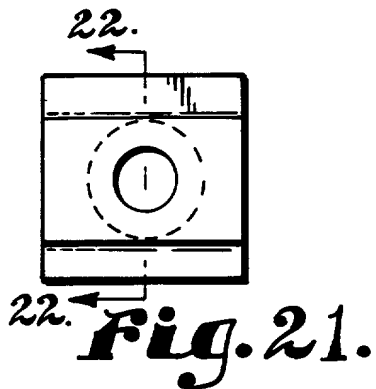


Fig. 21.



Fig. 22.

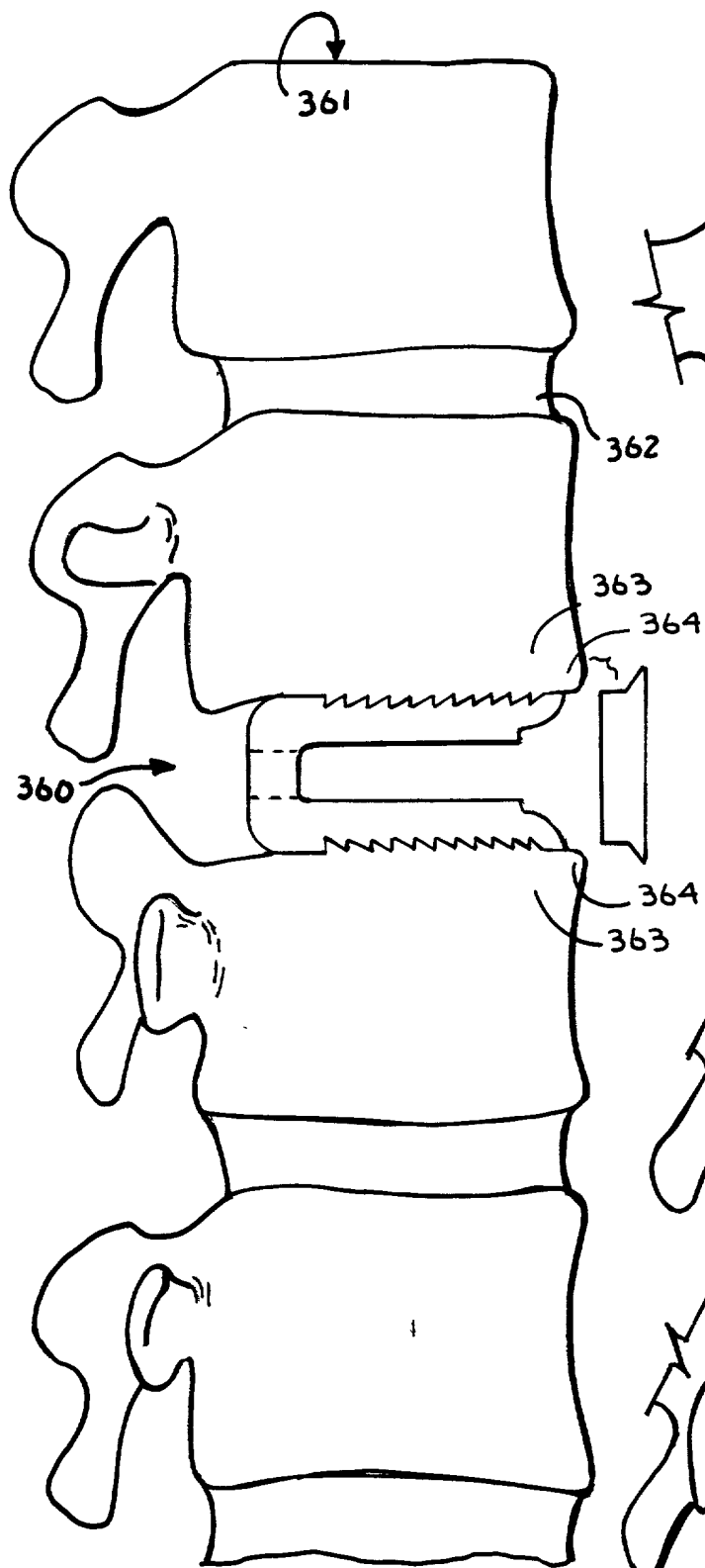


Fig. 23.

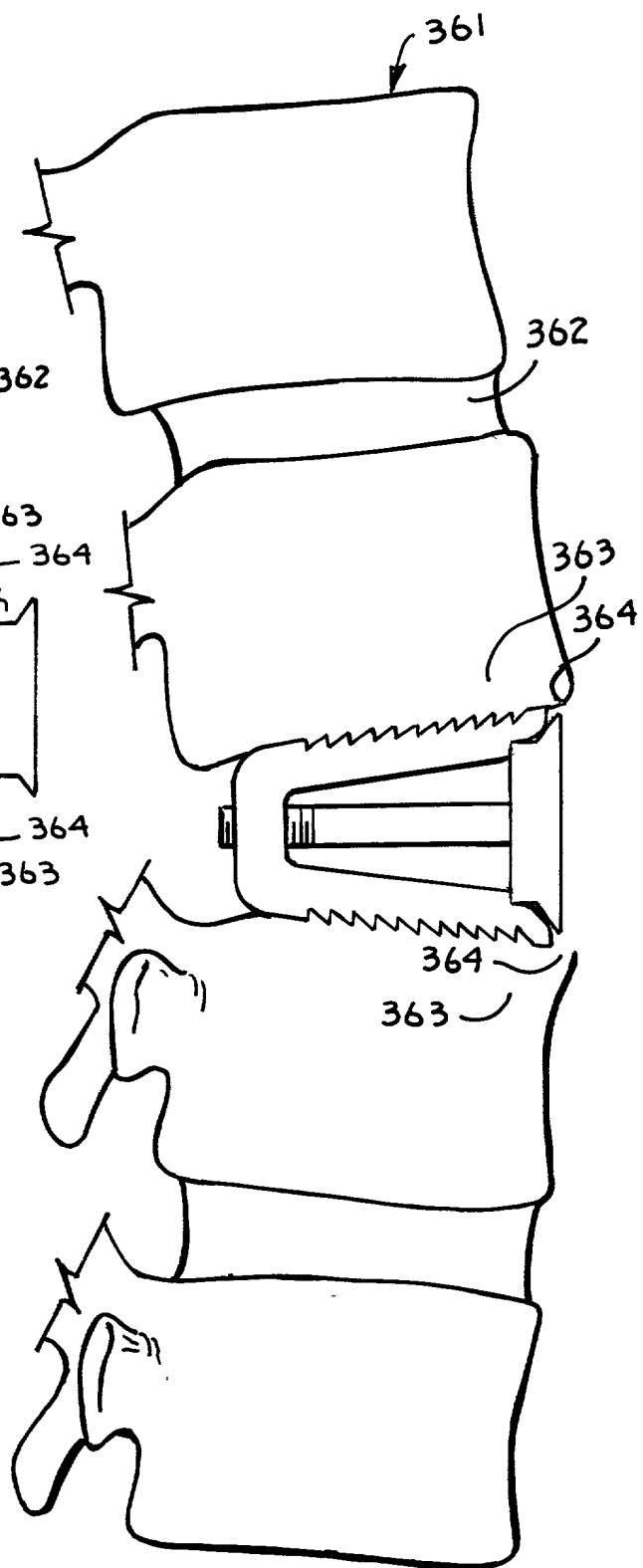


Fig. 24.



DECLARATION AND POWER OF ATTORNEY
FOR A PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as
stated below next to my name.

I believe I am the original, first and sole inventor of the
subject matter which is claimed and for which a patent is sought
on the invention entitled ANTERIOR EXPANDABLE SPINAL FUSION CAGE
SYSTEM, the specification of which is attached hereto.

I hereby state that I have reviewed and understand the
contents of the above-identified specification, including the
claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is
material to the patentability of this application in accordance
with Title 37, Code of Federal Regulations, Sec. 1.56. (Under
Sec. 1.56 information is material to patentability when it is not
cumulative to information already of record before the Patent and
Trademark Office with respect to the present application and it
establishes either by itself or in combination with other
information a prima facie case of unpatentability of a claim or
it refutes or is inconsistent with a position taken in opposing
an argument of unpatentability relied upon by the Patent and
Trademark Office or in asserting an argument of patentability.
Under this section a prima facie case of unpatentability is

established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.)


I hereby state that I do not know and do not believe that the invention was ever known or used in the United States of America before my invention thereof; that to the best of my knowledge and belief the invention has not been in public use or on sale in the United States of America more than one year prior to this application, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, or patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application; and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns.

003440 "E42560

I hereby appoint John C. McMahon, Reg. No. 29,415 and Malcolm A. Litman, Reg. No. 19,579, both members of the bar of the State of Missouri, whose postal address is PO Box 30069, Kansas City, Missouri 64112, telephone (816) 531-3470, as my attorneys, with full power of substitution, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent Office connected therewith in my behalf.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4-13-2000



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